DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 23, 2015

UE LifeSciences, Inc.
Mihir Shah
CEO
3711 Market Street, Suite 800
Philadelphia, PA 19104

Re: K142926
Trade/Device Name: iBreastExam
Regulation Number: 21 CFR 884.2990
Regulation Name: Breast lesion documentation system
Regulatory Class: II
Product Code: NKA
Dated: March 16, 2015
Received: March 20, 2015

Dear Mihir Shah,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142926

Device Name

iBreastExam

Indications for Use *(Describe)*

iBreastExam™ device is intended to produce a surface pressure map of the breast as an aid in documenting palpable breast lesions identified during a clinical breast exam. iBreastExam™ device is intended for use by a qualified healthcare professional trained in its use and is not for home use.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Applicant and Official Correspondent:

UE LifeSciences, Inc.
C/o Mihir B. Shah
3711 Market St, Suite 800
Philadelphia, PA 19104

Contact Person: Mihir Shah
Tel: 631-980-8340
Email: mihir@uelifesciences.com

Date Prepared: April 23, 2015

Name of Device:

iBreastExam
Classification Name: Breast Lesion Documentation System (12 CFR 884.2990)
Regulation Class: Class II
Product Code: NKA

Predicate Device:

BREASTVIEW® VISUAL MAPPING SYSTEM (K010514 granted through de novo process)

Intended Use:

The device is intended to produce a surface map of the breast as an aid in documenting size, shape, and location of breast lesions identified during a clinical breast exam. It is a documentation tool. It is not intended for diagnosis. The device should only be used to document a lesion already palpated on clinical breast exam. Clinical management decisions should only be made on the basis of the clinical and diagnostic examinations (e.g. ultrasound or mammography). If there is a disagreement between the examination and the record produced by the device, decisions should be made on the basis of the clinical examination.

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Indications for Use:

iBreastExam™ (iBreastExam) device is intended to produce a surface pressure map of the breast as an aid in documenting palpable breast lesions identified during a clinical breast exam. iBreastExam™ device is intended for use by a qualified healthcare professional trained in its use and is not for home use.

Technological Characteristics:

The iBreastExam system consists of a group of hardware and software components.
The hardware component(s) consist of:

- iBreastExam Scanhead
- Computer System
- USB Wall Charger and Charging Cables

The software component(s) consist of:

- iBEConnect Software Program

Performance Testing:

Performance tests were conducted per Class II Special Controls Guidance Document: Breast Lesion Documentation System, including electrical safety tests, electromagnetic compatibility tests as well as biocompatibility test. In addition, a side-by-side performance test was conducted between iBreastExam™ and the predicate device (BreastView).

Complete validation and verification was performed on all software and hardware subsystems. In summary, all test results were satisfactory and did not raise any additional safety or effectiveness concerns.

Substantial Equivalence:

Parameter	Subject device	Predicate device – BreastView Visual Mapping System
Intended use	Same as the predicate	is intended to produce a surface pressure map of the breast as an aid to document palpable breast lesions identified during a clinical breast exam.
Processing unit	Same as the predicate	Computer with software, Windows based operating system
Data acquisition method	Same as the predicate	Array of pressure sensors mounted on hand-held scanhead
Lesion documentation	Same as the predicate	Lesion size, location, stiffness, shape
Detectable lesion size	≥5mm	5-40mm
Number of sensors in imaging	16	416
Pressure sensor array size	28mm × 28mm	40mm × 25mm

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Image display	Same as the predicate	Yes
Image storage	Same as the predicate	Yes
Comparison to previous images	Same as the predicate	No
Final report	Same as the predicate	Color tactile maps
Patient contacting component	Reusable scanhead made of acrylonitrile butadiene styrene	Disposable, single use cover (made of polyurethane) attached to the scanhead
Use with lotion	Not needed	Needed

Substantial Equivalence Discussion

- Intended use – The subject and predicate devices have the same intended use.
- Technological characteristics – Similarities between the subject and predicate devices
    - They use computer with software, Windows based operating system.
    - They used the same data acquisition method – Array of pressure sensors mounted on hand-held scanhead.
    - They provide the same lesion documentation lesion size, location, stiffness, and shape.
    - They detect the similar lesion sizes.
    - They have the same features regarding image display, image storage, image comparison, and format of final report.
- Technological characteristics – Differences between the subject and predicate devices
    - The subject imaging component contains 16 sensors whereas the predicate imaging component has 416 sensors. Also, the subject device has a smaller pressure sensor array size. The differences raise an effectiveness concern, but there is no new type of question. Bench testing data showed that the subject device is effective.
    - The subject device uses different material (ABS vs. polyurethane used in the predicate device), raising a safety concern. However, safety related to material is not a new type of question and can be assessed by accepted biocompatibility testing. Biocompatibility data demonstrated that the subject device is safe.

In conclusion, the subject device is substantial equivalent in terms of safety and effectiveness.